

AUG 13 1996

510(k) Summary

as required by 21 CFR 807.92

Device Name: Unscented Menstrual Tampon

Manufacturer: Tambrands Inc.
Bridge & Springfield Streets
Palmer, MA 01069

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Date Summary Prepared: June 17, 1996**Device Names:**

Trade Name: TAMPAX Tampons, Plastic Applicator
Common Name: TAMPAX Tampons
Classification Name: Unscented Menstrual Tampons (21 CFR 884.5470)

Legally Marketed Device: TAMPAX Tampons, Plastic Applicator

Device Description: TAMPAX Tampons, Plastic Applicator will be provided in three absorbencies, regular, super and super plus. TAMPAX Tampons, Plastic Applicator have a colored plastic applicator. TAMPAX Tampons, Plastic Applicator are made of rayon fibers and overwrap, a cotton withdrawal cord, and a colored plastic applicator.

Intended Use: TAMPAX Tampons, Plastic Applicator are unscented menstrual tampons used to absorb menstrual fluid.

How Product Differs from Predicate Device: The new device has a colored applicator. Except for the color of the applicator, TAMPAX Tampons, Plastic Applicator are identical to the predicate product. The colorants used in the colored applicator have been adequately characterized and evaluated using scientifically valid safety tests.

Assessment of Performance Data:

Non-clinical Testing: Biocompatibility testing of the colorants and the colored applicator used in TAMPAX Tampons, Plastic Applicator was conducted. In addition to the review of existing literature and toxicological data, the following tests were conducted related to the safety of TAMPAX Tampons, Plastic Applicator:

- Irritation and sensitization testing
- Cytotoxicity testing
- Extraction assay

The results of these tests demonstrate that TAMPAX Tampons, Plastic Applicator are equivalent in terms of their safety and effectiveness to legally marketed tampons.

Clinical Testing: A clinical study was done to evaluate the safety of TAMPAX Tampons, Plastic Applicator and to compare its safety to its predicates. The study compared insertion of TAMPAX Tampons, Plastic Applicator to insertion of control tampons during intermenstrual use in 57 women. Safety was evaluated by comparing the prevalence of product related irritation after tampon insertion.

The study results showed no differences in product related irritation or comfort between TAMPAX Tampons, Plastic Applicator and the control product. No significant or unexpected adverse events were observed during the study.

Conclusions: Results of the non-clinical and clinical tests showed that the addition of colorant to the Plastic Applicator does not alter the safety or effectiveness of the device and that TAMPAX Tampons, Plastic Applicator are as safe and as effective as predicate, legally marketed tampons. Further, the results demonstrated that TAMPAX Tampons, Plastic Applicator are substantially equivalent to other legally marketed tampons.